

Application No. 10/044,300
Amendment dated August 7, 2003
Reply to Office action of May 07, 2003
Docket Number 22727/04066

REMARKS/ARGUMENTS

The specification is amended in the title to comport with the amendments to the claims. The amendment to the specification does not add any new matter.

Claims 1-20 are pending in this application. Claims 1-20 are rejected. Claims 2 and 3 are hereby cancelled without prejudice or disclaimer. Claims 1, 6, 11, 12, 13, 14, 15, 16, 17, 19 and 20 are hereby amended, and new claims 21-23 are hereby added. Support for amendment to claims 1, 12, 13 and 16 is found at paragraphs [0006], [0032], [0033], [0054] and original claim 4. Support for amendment to claim 6 is found in original claim 13. Support for amendments to claims 11 and 12, and for new claim 23 is found at paragraph [0057], lines 1-13, and [0029], lines 6 and 15-24. Support for new claims 21 and 22 is found in original claims 14 and 15. The amendments and new claims do not introduce any new matter.

In consideration of the amendments and the following remarks, reconsideration of claims 1 and 4-20, and consideration of new claims 21-23 are respectfully requested.

Information Disclosure Statement

As requested by the Patent Office, Applicant has submitted herewith a Supplemental Information Disclosure Statement which includes a copy of the reference identified in the office action showing the date of publication, volume number, and page numbers.

Claim Objections

The Patent Office has objected to claims 1, 3 and 12 for informalities. The claims have been amended consistent with the suggestions of the Patent Office. It is submitted that these amendments overcome the objections.

Claim Rejections - 35 USC § 112, second paragraph. Indefiniteness

Claims 1-11 and 16-20 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. Claims 1, 16 and 20 have been amended for clarity consistent with the suggestions of the Patent Office. It is submitted that these amendments overcome the rejection of these claims, and Applicant respectfully requests withdrawal of the rejections.

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Claim Rejections - 35 USC § 112, first paragraph, scope of enablement

Applicant respectfully requests reconsideration of claims 11-15 and 17 which have been rejected under 35 U.S.C. §112, first paragraph, as not enabled.

Claims 11 and 12 have been amended for clarity to recite an anthocyanin regulatory gene selected from the group consisting of an R gene, a combination of a C1 gene and an R gene, a C1/R gene and a DNA construct encoding a chimeric CRC protein. In connection with each of these claims the Patent Office has stated that the specification does not teach any "chimeric C1/R gene." Applicant has amended the claims for clarity to recite discretely a C1/R gene and a DNA construct encoding a chimeric CRC protein; each of these discretely recited polynucleotides are identified in the specification at paragraph [0029] (lines 1-8 for C1/R, and lines 15-24 for chimeric CRC protein) as choices for anthocyanin regulatory genes for use in accordance with the disclosed invention.

The Patent Office has also stated in connection with claims 11 and 12 that "the specification does not enable the production of transgenic grass with a different color phenotype by transforming the grass with a C1 gene alone ... as this gene product alone will not produce any effect." Claims 11 and 12 have been amended to delete the recitation of the C1 gene alone, thus rendering moot this rejection.

Claim 13, as amended, recites an inducible promoter for use in the nucleic acid construct of claim 12, which comprises one or more of the promoters selected from the group consisting of several known plant stress-inducible promoters. The Patent Office has stated that "the specification does not provide any guidance in how one may combine any of the promoters to form a single promoter that is still inducible." Applicant submits that neither the claims nor the specification suggests any molecular construct comprising a combination of all or portions of more than one promoter to form a single promoter. Instead, as recited in claim 13, Applicant has disclosed a construct according to claim 12 which comprises one or more of the specifically recited promoters positioned in series and operably linked to the anthocyanin regulatory gene. Specific guidance regarding the requirements for use of any one or more of the recited promoters can be found in the corresponding references cited in paragraphs [0032] - [0034]. At the time the instant application was filed, one of ordinary skill in the art would be able to prepare a construct

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according to claim 13 using one or more of the listed promoters to control expression of the anthocyanin gene.

The Patent Office has rejected claim 17 for lack of enablement, and has stated that "undue experimentation would be required by one skilled in the art to determine how all of the transformation methods listed in claim 17 can be used to transform all grass species." In making this rejection, the Patent Office has stated that *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ 2d 1001, 1005 (Fed. Cir. 1997) "teaches that 'the specification, not the knowledge of one skilled in the art' must supply the enabling aspects of the invention." Applicant respectfully submits that the Patent Office has misconstrued the meaning of the Federal Circuit in connection with rejection of claim 17. The rule stated in *Genentech* pertains to the disclosure of the "novel aspects of an invention."

Applicant submits that the choice of technique for transformation of a plant cell, as recited in claim 17, is not a novel aspect of Applicant's invention. Moreover, Applicant maintains that the various techniques for transformation which are listed in claim 17 are indeed well known in the art, and Applicant is not required to disclose what is well known in the art. The Federal Circuit acknowledged in *Genentech* "that a specification need not disclose what is well known in the art," but it qualified that statement by recognizing that the "general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. ... [W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art."

The specification does fully enable the novel aspects of the invention as recited in claim 17, which are embodied in the production of transgenic plants using a DNA construct comprising an exogenous anthocyanin regulatory gene operably linked to an inducible transcriptional regulating promoter. Applicant has described selection of anthocyanin regulatory genes and promoters, i.e., the starting materials for making a construct, and has likewise provided specific examples of, and sources for obtaining and preparing anthocyanin regulatory genes and gene constructs (see paragraphs [0022] through [0029]), and promoters (see paragraphs [0031] through [0035]). Applicant has provided guidance regarding selection of other gene regulatory

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elements for inclusion in the DNA constructs recited in claim 17, and in construct preparation (see paragraphs [0034] and [0039] through [0043]). Applicant has also detailed the steps by which the method of claim 17 is carried out, including a working example of transformation using microprojectile bombardment (see Paragraphs [0049] and [0059]), and description of the steps whereby transformation is confirmed (see paragraphs [0050] thorough [0052]).

Applicant respectfully submits that the selection of transformation technique is incidental to, and is not a novel aspect of the invention. Nevertheless, as noted above, Applicant has provided specific guidance regarding transformation, and has discretely identified several alternative techniques for transformation, together with citations to references in the art which more fully disclose those techniques (see paragraph [0028]). With all of this guidance, one of ordinary skill in the art would be able to construct a transgene, select and employ a suitable technique for its introduction into a plant cell or protoplast, and confirm successful transformation without undue experimentation.

For the foregoing reasons, Applicant submits that claims 11-15 and 17 are enabled, and Applicant respectfully requests withdrawal of the rejection of these claims.

Claim Rejections - 35 USC § 103 (a)

Applicant respectfully requests reconsideration of claims 1 and 4-20 which have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Bhalla et. al., (WO 96/22015) in combination with Lloyd et. al., (Science 1992).

Independent claims 1, 12 and 16, as amended, recite a nucleic acid construct which is used to provide a transgenic grass plant whose color phenotype changes in response to the plant's contact with a chemical or stress conditions. This nucleic acid construct comprises an exogenous anthocyanin regulatory gene operably linked to an inducible promoter. As further recited in claims 1 and 16, the promoter is responsive to contact of the transgenic grass plant with a chemical or stress conditions, wherein a change in the color phenotype of the transgenic grass plant signals response of the transgenic grass plant to a chemical or stress conditions. Bhalla teaches transformation of grass tissues using the technique of microparticle bombardment to produce transgenic grass plants that have altered characteristics. Bhalla does not teach any transgenic grass plant whose color phenotype changes. Bhalla does not teach or suggest any

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methods for specifically altering the expression of plant pigmentation. As noted by the Patent Office, Bhalla makes not mention any genes that affect plant pigmentation, and Bhalla does not teach or suggest any inducible promoters for any use, much less for controlling expression of a transgene based on environmental conditions.

Lloyd does not provide what Bhalla lacks. Lloyd teaches transformed Arabidopsis and tobacco plants which have augmented anthocyanin pigmentation. And though Lloyd teaches use of the maize C and R genes under control of a constitutive, i.e., a non-inducible promoter, nowhere does Lloyd teach or suggest use of the maize C1/R gene or a construct encoding a chimeric CRC protein, as recited in amended claims 11 and 12, and new claim 23. Moreover, like Bhalla, Lloyd does not teach any inducible promoters which permit transgenic plants to signal changed environmental conditions through altered pigmentation. There is no motivation in Bhalla to utilize any type of inducible promoter to control any characteristic, much less to use stress or chemical inducible promoters to control pigment phenotype. And there is no suggestion in Bhalla or Lloyd that any promoters other than those specifically described in those references should be used to achieve expression of transgenes.

Even when combined, Bhalla and Lloyd do not provide transgenes, or grasses transformed therewith which communicate the existence of stress conditions or chemical induction through pigment changes, as recited in the instant claims. In addition to lacking any teaching or suggestion of any inducible promoters, neither of these references suggests the desirability of any form of inducible control of transgene expression. Neither Bhalla nor Lloyd mentions any conditions or chemicals to which a promoter might be responsive, such as lack of fertilizer, lack of water, pathogen infection, or chemical agents, as recited in claims 5, 7, 8, 12 and 19, as amended. And neither of these references mentions any stress-inducible promoters, such as the maize rab28, rab17 and Ivr2 gene promoters, and the hydroxyproline-rich glycoprotein gene promoter, which are recited in amended claims 6 and 13.

The Patent Office has mentioned a reference cited by Applicant (see paragraph [0033], lines 8-9, Lloyd, 1994, hereinafter "Lloyd 1994") as being an admission of prior art regarding chemical-inducible promoters. Applicant wishes to clarify that the cited reference is provided merely as an example of one technique used in the art for achieving steroid-dependent expression

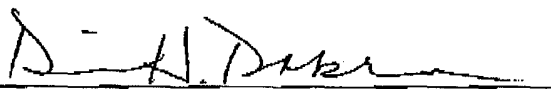
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of a chimeric protein. Expression of the chimeric protein described in Lloyd 1994 is achieved by steroid hormone receptors, not by a gene promoter; the construct encoding the chimeric protein uses a promoter that is not inducible. Thus, like Bhalla and Lloyd, Lloyd 1994 does not teach or suggest the use of an inducible promoter which is operably linked to an anthocyanin regulatory gene, as recited in amended claims 1, 12, and 16, and their dependent claims. Based on the foregoing, Applicant submits that the combination of Bhalla and Lloyd, even in view of Lloyd 1994, does not render obvious the inventions recited in independent claims 1, 12 and 16; claims 4-9, 10-11, 13-15 and 17-20 depend from independent claims 1, 12 and 16, and for the reasons given above, are likewise not rendered obvious by Bhalla and Lloyd. Applicant respectfully requests withdrawal of rejection of these claims. Claims 2 and 3 have been cancelled, rendering moot the rejection of those claims.

In view of the above-described amendments and remarks, it is submitted that claims 1 and 4-20, and new claims 21-23 are in condition for allowance. Prompt notice of such allowance is respectfully requested.

Respectfully submitted,

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